

## SECTION 1

### INTRODUCTION

#### 1.1 HISTORICAL PERSPECTIVE

Contamination of aquatic resources, including freshwater, estuarine, and marine fish and shellfish, has been documented in the scientific literature for many regions of the United States (NAS, 1991). Environmental concentrations of some pollutants have decreased over the past 25 years as a result of better water quality management practices. However, environmental concentrations of other heavy metals, pesticides, and toxic organic compounds have increased due to intensifying urbanization, industrial development, and use of new agricultural chemicals. Our Nation's waterbodies are among the ultimate repositories of pollutants released from these activities. Pollutants come from permitted point source discharges (e.g., industrial and municipal facilities), accidental spill events, and nonpoint sources (e.g., agricultural practices, resource extraction, urban runoff, in-place sediment contamination, groundwater recharge, vehicular exhaust, and atmospheric deposition from various combustion and incineration processes).

Once these toxic contaminants reach surface waters, they may concentrate through aquatic food chains and bioaccumulate in fish and shellfish tissues. Aquatic organisms may bioaccumulate environmental contaminants to more than 1,000,000 times the concentrations detected in the water column (U.S. EPA, 1992c, 1992d). Thus, fish and shellfish tissue monitoring serves as an important indicator of contaminated sediments and water quality problems, and many states routinely conduct chemical contaminant analyses of fish and shellfish tissues as part of their comprehensive water quality monitoring programs (Cunningham and Whitaker, 1989; Cunningham, 1998; Cunningham and Sullivan, 1999). Tissue contaminant monitoring also enables state agencies to detect levels of contamination in fish and shellfish tissue that may be harmful to human consumers. If states conclude that consumption of chemically contaminated fish and shellfish poses an unacceptable human health risk, they may issue local fish consumption advisories or bans for specific waterbodies and specific fish and shellfish species for specific populations.

In 1989, the American Fisheries Society (AFS), at the request of the U.S. Environmental Protection Agency (EPA), conducted a survey of state fish and shellfish consumption advisory practices. Questionnaires were sent to health departments, fisheries agencies, and water quality/environmental management departments in all 50 states and the District of Columbia. Officials in all 50 states and the District responded.

Respondents were asked to provide information on several issues including

- Agency responsibilities
- Sampling strategies
- Sample collection procedures
- Chemical residue analysis procedures
- Risk assessment methodologies
- Data interpretation and advisory development
- State concerns
- Recommendations for federal assistance.

Cunningham et al. (1990) summarized the survey responses and reported that monitoring and risk assessment procedures used by states in their fish and shellfish advisory programs varied widely. States responded to the question concerning assistance from the federal government by requesting that federal agencies

- Provide a consistent approach for state agencies to use in assessing health risks from consumption of chemically contaminated fish and shellfish
- Develop guidance on sample collection procedures
- Develop and/or endorse uniform, cost-effective analytical methods for quantitation of contaminants
- Establish a quality assurance (QA) program that includes use of certified reference materials for chemical analyses.

In March 1991, the National Academy of Sciences (NAS) published a report entitled *Seafood Safety* (NAS, 1991) that reviewed the nature and extent of public health risks associated with seafood consumption and examined the scope and adequacy of current seafood safety programs. After reviewing over 150 reports and publications on seafood contamination, the NAS Institute of Medicine concluded that high concentrations of chemical contaminants exist in various fish species in a number of locations in the country. The report noted that the fish monitoring data available in national and regional studies had two major shortcomings that affected their usefulness in assessing human health risks:

- In some of the more extensive studies, analyses were performed on nonedible portions of finfish (e.g., liver tissue) or on whole fish, which precludes accurate determination of human exposures.
- Studies did not use consistent methods of data reporting (e.g., both geometric and arithmetic means were reported in different studies) or failed to report crucial information on sample size, percent lipid, mean values of contaminant concentrations, or fish size, thus precluding direct comparison of the data from different studies and complicating further statistical analysis and risk assessment.

### **1.1.1 Establishment of the Fish Contaminant Workgroup**

As a result of NAS concerns and state concerns expressed in the AFS survey, EPA's Office of Water established a Fish Contaminant Workgroup. It was composed of representatives from EPA and the following state and federal agencies:

- U.S. Food and Drug Administration (FDA)
- U.S. Fish and Wildlife Service (FWS)
- Ohio River Valley Water Sanitation Commission (ORSANCO)
- National Oceanic and Atmospheric Administration (NOAA)
- Tennessee Valley Authority (TVA)
- United States Geological Survey (USGS)

and representatives from 26 states: Alabama, Arkansas, California, Colorado, Delaware, Florida, Georgia, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Texas, Virginia, and Wisconsin.

The objective of the EPA Fish Contaminant Workgroup was to formulate guidance for states on how to sample and analyze chemical contaminants in fish and shellfish where the primary end uses of the data included development of fish consumption advisories. The Workgroup compiled documents describing protocols currently used by various federal agencies, EPA Regional offices, and states that have extensive experience in fish contaminant monitoring. Using these documents, they selected methods considered most cost-effective and scientifically sound for sampling and analyzing fish and shellfish tissues. These methods were recommended as standard procedures for use by the states and are described in this guidance document.

### **1.1.2 Development of a National Fish Advisory Database**

In addition to initiating work on the national guidance document series in 1993, EPA also initiated work on the development of a national database — The National Listing of Fish and Wildlife Advisories (NLFWA) database — for tracking fish and wildlife advisories issued by the states. The 1998 update of the NLFWA database includes all available information describing state, territorial, tribal, and federal fish consumption advisories issued in the United States (U.S. EPA 1999a, 1999c). The database contains fish consumption advisory information provided to EPA by the states and other jurisdictions from 1993 through December 1998. It also includes information from 1996 through 1997 for 12 Canadian provinces and territories. No updates to information on Canadian advisories were made in 1998. Since the release of the first fish advisory results in 1994, advisory results and trends have been accessible to states, territories, tribal organizations, and the general public by querying the NLFWA database or through summary information reported each year in the *EPA Fact Sheet—Update: National Listing of Fish and*

*Wildlife Advisories.* Fish advisory results and trends reported in the 1999 Fish Advisory Fact Sheet (U.S. EPA, 1999c) are presented below. The most recent updates of the Fish Advisory Fact Sheet are available on the EPA website at <http://epa.gov/OST/fish>.

#### 1.1.2.1 Background—

The states, U.S. territories, and Native American tribes (hereafter referred to as states) have primary responsibility for protecting residents from the health risks of consuming contaminated noncommercially caught fish and wildlife. They do this by issuing consumption advisories for the general population, including recreational and subsistence fishers, as well as for sensitive subpopulations (such as pregnant women, nursing mothers, and children). These advisories inform the public that high concentrations of chemical contaminants (e.g., mercury and dioxins) have been found in local fish and wildlife. The advisories include recommendations to limit or avoid consumption of certain fish and wildlife species from specified waterbodies or, in some cases, from specific waterbody types (e.g., all inland lakes). Similarly, in Canada, the provinces and territories have primary responsibility for issuing fish consumption advisories for their residents.

States typically issue five major types of advisories and bans to protect both the general population and specific subpopulations.

- When levels of chemical contamination pose a health risk to the general public, states may issue a no consumption advisory for the general population.
- When contaminant levels pose a health risk to sensitive subpopulations, states may issue a no consumption advisory for the sensitive subpopulation.
- In waterbodies where chemical contamination is less severe, states may issue an advisory recommending that either the general population or a sensitive subpopulation restrict their consumption of the specific species for which the advisory is issued.
- The fifth type of state-issued advisory is the commercial fishing ban, which prohibits the commercial harvest and sale of fish, shellfish, and/or wildlife species from a designated waterbody and, by inference, the consumption of all species identified in the fishing ban from that waterbody.

As shown in Table 1-1, advisories of all types increased overall in number from 1993 to 1998.

#### 1.1.2.2 Advisories in Effect—

The database includes information on

- Species and size ranges of fish and/or wildlife sampled
- Chemical contaminants identified in the advisory

**Table 1-1. U.S. Advisories Issued from 1993 to 1998 by Type**

	1993	1994	1995	1996	1997	1998
No Consumption – General Population	503	462	463	563	545	532
No Consumption – Sensitive Subpopulation	555	720	778	1,022	1,119	1,211
Restricted Consumption – General Population	993	1,182	1,372	1,763	1,843	2,062
Restricted Consumption – Sensitive Subpopulation	689	900	1,042	1,370	1,450	1,595
Commercial Fishing Ban	30	30	55	50	52	50

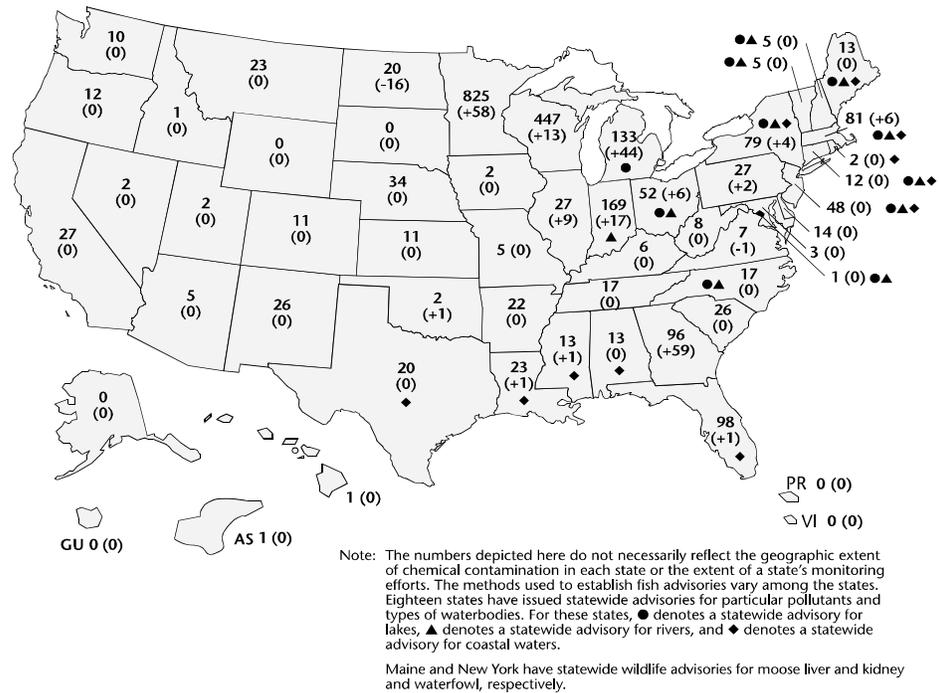
Source: U.S. EPA 1999a, 1999c.

- Geographic location of each advisory (including narrative information on landmarks, river miles, or latitude and longitude coordinates of the affected waterbody and map showing location of waterbody)
- Lake acreage or river miles under advisory
- Population for whom the advisory was issued
- Fish tissue chemical residue data from waterbodies under advisory.

The 1994, 1995, 1996, 1997, and 1998 versions of the NLFWA database can generate national, regional, and state maps that illustrate any combination of these advisory parameters. In addition, the 1996 through 1998 versions of the database can provide information on the percentage of waterbodies in each state currently under an advisory and the percentage of waters assessed. A new feature of the 1998 database provides users access to fish tissue residue data for those waterbodies under advisory in 16 states. The name of each state contact, phone number, FAX number, and e-mail address are also provided so that users can obtain additional information concerning specific advisories. Comparable advisory information (excluding tissue residue data) and contact information for 1996 and 1997 are provided for each Canadian province or territory.

### 1.1.2.3 Advisory Trends—

The number of waterbodies in the United States under advisory reported in 1998 (2,506) represents a 9% increase from the number reported in 1997 (2,299 advisories) and a 98% increase from the number of advisories issued since 1993 (1,266 advisories). Figure 1-1 shows the number of advisories in effect for each state in 1998 and the number of advisories issued or rescinded since 1997. The increase in advisories issued by the states generally reflects an increase in the number of assessments of the levels of chemical contaminants in fish and wildlife tissues. These additional assessments were conducted as a result of the increased awareness of health risks associated with the consumption of chemically contaminated fish and wildlife. Some of the increase in advisory numbers, however, may be due to the increasing use of EPA risk assessment procedures in setting advisories rather than FDA action levels developed for commercial fisheries.

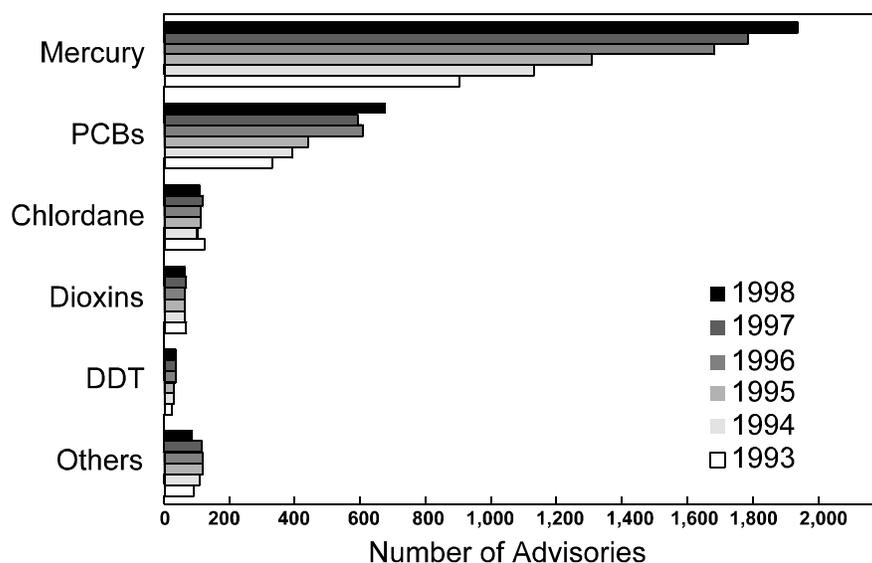


Source: U.S. EPA, 1999c.

**Figure 1-1. Total number of fish advisories in effect in each state in 1998 (change from 1997).**

**1.1.2.4 Bioaccumulative Pollutants—**

Although U.S. advisories have been issued for a total of 46 chemical contaminants, most advisories issued have involved five primary contaminants. These chemical contaminants are biologically accumulated in the tissues of aquatic organisms at concentrations many times higher than concentrations in the water. In addition, these chemical contaminants persist for relatively long periods in sediments where they can be accumulated by bottom-dwelling organisms and passed up the food chain to fish. Concentrations of these contaminants in the tissues of aquatic organisms may be increased at each successive level of the food chain. As a result, top predators in a food chain, such as largemouth bass, salmon, or walleye, may have concentrations of these chemicals in their tissues that can be a million times higher than the concentrations in the water. Mercury, PCBs, chlordane, dioxins, and DDT (and its degradation products, DDE and DDD) were at least partly responsible for 99 percent of all fish consumption advisories in effect in 1998. (See Figure 1-2.)



Source: U.S. EPA, 1999a, 1999c.

**Figure 1-2. Trends in number of advisories issued for various pollutants.**

#### 1.1.2.5 Wildlife Advisories—

In addition to advisories for fish and shellfish, the database also contains several wildlife advisories. Four states have issued consumption advisories for turtles: Arizona (3), Massachusetts (1), Minnesota (8), and New York (statewide advisory). One state (Massachusetts) has an advisory for frogs, New York has a statewide advisory for waterfowl (including mergansers), Arkansas has an advisory for woodducks, and Utah has an advisory for American coot and ducks. Maine issued a statewide advisory for moose liver and kidneys due to cadmium levels. No new wildlife advisories were issued in 1998.

#### 1.1.2.6 1998 United States Advisories—

The 1998 database lists 2,506 advisories in 47 states, the District of Columbia, and the U.S. Territory of American Samoa. Some of these advisories represent statewide advisories for certain types of waterbodies (e.g., lakes, rivers, and/or coastal waters). An advisory may represent one waterbody or one type of waterbody within a state's jurisdiction. Statewide advisories are counted as one advisory. The database counts one advisory for each waterbody name or type of waterbody regardless of the number of fish or wildlife species that are affected or the number of chemical contaminants detected at concentrations of human health concern. Eighteen states (Alabama, Connecticut, District of Columbia, Florida, Indiana, Louisiana, Maine, Massachusetts, Michigan, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Rhode Island, Texas,

and Vermont) currently have statewide advisories in effect (see Table 1-2). Missouri rescinded its statewide advisories for lakes and rivers in 1998, and Mississippi added a statewide coastal advisory for mercury. A statewide advisory is issued to warn the public of the potential for widespread contamination of certain species of fish in certain types of waterbodies (e.g., lakes, rivers and streams, or coastal waters) or certain species of wildlife (e.g., moose or waterfowl). In such a case, the state may have found a level of contamination of a specific pollutant in a particular fish or wildlife species over a relatively wide geographic area that warrants advising the public of the situation.

The statewide advisories and 2,506 specifically named waterbodies represent approximately 15.8 percent of the Nation's total lake acreage and 6.8% of the Nation's total river miles. In addition, 100 percent of the Great Lakes waters and their connecting waters are also under advisory due to one or more contaminants (e.g., PCBs, dioxins, mercury, and/or chlordane). The Great Lakes waters are considered separately from other lakes, and their connecting waters are considered separately from other river miles.

Several states also have issued fish advisories for all of their coastal waters. Using coastal mileages calculated by the National Oceanic and Atmospheric Administration (NOAA), an estimated 58.9 percent of the coastline of the contiguous 48 states currently is under advisory. This includes 61.5 percent of the Atlantic Coast and 100 percent of the Gulf Coast. No Pacific Coast state has issued a statewide advisory for any of its coastal waters although several localized areas along the Pacific Coast are under advisory. The Atlantic coastal advisories have been issued for a wide variety of chemical contaminants including mercury, PCBs, dioxins, and cadmium, while all of the Gulf Coast advisories have been issued for mercury.

### 1.1.2.7 Database Use and Access—

The NLFWA database was developed by EPA to help federal, state, and local government agencies and Native American tribes assess the potential for human health risks associated with consumption of chemical contaminants in noncommercially caught fish and wildlife. The data contained in this database may also be used by the general public to make informed decisions about the waterbodies in which they choose to fish or harvest wildlife; the frequency with which they fish these waterbodies; the species, size, and number of fish they collect; and the frequency with which they consume fish from specific waterbodies. Note: State fish advisory contact information and hyperlinks to state fish advisory websites are also provided.

EPA provides this 1998 update of the NLFWA database available on the Internet at

<http://www.epa.gov/OST/fish>

**Table 1-2. Summary of Statewide Advisories in Effect in 1998**

State	Lakes	Rivers	Coastal Waters
Alabama	—	—	Mercury
Connecticut	Mercury	Mercury	PCBs
District of Columbia	PCBs	PCBs	—
Florida	—	—	Mercury
Indiana	—	Mercury PCBs	—
Louisiana	—	—	Mercury
Maine	Mercury	Mercury	Dioxins
Massachusetts	Mercury	Mercury	PCBs Organics
Michigan	Mercury	—	—
Mississippi	—	—	Mercury
New Hampshire	Mercury	Mercury	PCBs
New Jersey	Mercury	Mercury	PCBs Cadmium Dioxins
New York	PCBs Chlordane Mirex DDT	PCBs Chlordane Mirex DDT	PCBs Cadmium Dioxins
North Carolina	Mercury	Mercury	—
Ohio	Mercury	Mercury	—
Rhode Island	—	—	PCBs
Texas	—	—	Mercury
Vermont	Mercury	Mercury	—

Source: U.S. EPA, 1999a, 1999c.

Further information on specific advisories within a particular state is available from the appropriate state agency contact listed in the database. This is particularly important for advisories recommending that consumers restrict their consumption of fish from certain waterbodies. State health departments provide more specific information for restricted consumption advisories (RGP and RSP) on the appropriate meal size and meal frequency (number of meals per week or month) that is considered safe to consume for a specific consumer group (e.g., the general public versus pregnant women, nursing mothers, and young children). For further information on Canadian advisories, contact the appropriate Province contact given in the database.

For more information concerning the National Fish and Wildlife Contamination Program, contact:

U.S. Environmental Protection Agency  
Office of Science and Technology  
National Fish and Wildlife Contamination Program—4305  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
Phone 202 260-7301 FAX 202 260-9830  
e-mail: Bigler.Jeff@epa.gov

**1.2 PURPOSE**

The purpose of this manual is to provide overall guidance to states on methods for sampling and analyzing contaminants in fish and shellfish tissue that will promote consistency in the data they use to determine the need for fish consumption advisories. This manual provides guidance only and does not constitute a regulatory requirement for the states. It is intended to describe what EPA believes to be scientifically sound methods for sample collection, chemical analyses, and statistical analyses of fish and shellfish tissue contaminant data for use in fish contaminant monitoring programs that have as their objective the protection of public health. This nonregulatory, technical guidance manual is intended for use as a handbook by state and local agencies that are responsible for sampling and analyzing fish and shellfish tissue. Adherence to this guidance will enhance the comparability of fish and shellfish contaminant data, especially in interstate waters and thus provide more standardized information on fish contamination problems.

It should be noted that the EPA methodology described in Volumes 1 and 2 of this guidance series offers great flexibility to state users. These documents are designed to meet the objectives of state monitoring and risk assessment programs by providing options to meet specific state or study needs within state budgetary constraints. The users of this fish advisory guidance document should recognize that it is the consistent application of the EPA methodology and processes rather than individual elements of the program sampling design that are of major importance in improving consistency among state fish advisory programs. For example, whether a state elects to collect three composite samples of five individual fish or four composite samples of eight individual fish as the basis of its state program is of less importance than a state designing and executing its monitoring program with attention to all elements of the EPA methodology having been considered and addressed during the planning and implementation phases.

One major factor currently affecting the comparability of fish advisory information nationwide, is the fact that the states employ different methodologies to determine the necessity for issuing an advisory. For example, some states currently do not use the EPA methodology at all or use it only in their assessment of health risks for certain chemical contaminants. Often these states rely instead on exceedances of FDA action levels or tolerances to determine the need to issue an advisory. FDA's mission is to protect the public health with respect to levels of chemical contaminants in all foods, including fish and shellfish sold in interstate commerce. FDA has developed both action levels and tolerances to address levels of contamination in foods. FDA may establish an action level when food contains a chemical from sources of contamination that cannot be avoided even by adherence to good agricultural or manufacturing practices, such as

contamination by a pesticide that persists in the environment. An action level is an administrative guideline or instruction to the agency field unit that defines the extent of contamination at which FDA may regard food as adulterated. An action level represents the limit at or above which FDA may take legal action to remove products from the marketplace. Under the Food, Drug, and Cosmetic Act, FDA also may set tolerances for unavoidably added poisonous or deleterious substances, that is, substances that are either required in the production of food or are otherwise unavoidable by good manufacturing practices. A tolerance is a regulation that is established following formal rulemaking procedures; an action level is a guideline or "instruction" and is not a formal regulation (Boyer et al., 1991).

FDA's jurisdiction in setting action levels or tolerances is limited to contaminants in food shipped and marketed in interstate commerce. Thus, the methodology used by FDA in establishing action levels or tolerances is directed at determining the health risks of chemical contaminants in fish and shellfish that are bought and sold in interstate commerce rather than in locally harvested fish and shellfish (Bolger et al., 1990). FDA action levels and tolerances are indicators of chemical residue levels in fish and shellfish that should not be exceeded for the general population who consume fish and shellfish typically purchased in supermarkets or fish markets that sell products that are harvested from a wide geographic area, including imported fish and shellfish products. However, the underlying assumptions used in the FDA methodology were never intended to be protective of recreational, tribal, ethnic, and subsistence fishers who typically consume larger quantities of fish than the general population and often harvest the fish and shellfish they consume from the same local waterbodies repeatedly over many years. If these local fishing and harvesting areas contain fish and shellfish with elevated tissue levels of chemical contaminants, these individuals potentially could have increased health risks associated with their consumption of the contaminated fish and shellfish.

The following chemical contaminants discussed in this volume have FDA action levels for their concentration in the edible portion of fish and shellfish: chlordane, DDT, DDE, DDD, heptachlor epoxide, mercury, and mirex. FDA has not set an action level for PCBs in fish but has established a tolerance in fish for this chemical. Table 1-3 compares the FDA action levels and tolerance for these six chemical contaminants with EPA's recommended screening values (SVs) for recreational and subsistence fishers calculated for these target analytes using the EPA methodology.

The EPA SV for each chemical contaminant is defined as the concentration of the chemical in fish tissue that is of potential public health concern and that is used as a threshold value against which tissue residue levels of the contaminant in fish and shellfish can be compared. The SV is calculated based on both the

**Table 1-3. Comparison of FDA Action Levels and Tolerances with EPA Screening Values**

Chemical contaminant	FDA Action Level <sup>a</sup> (ppm)	EPA SV for Recreational Fishers (ppm)	EPA SV for Subsistence Fishers (ppm)
Chlordane	0.3	0.114	0.014
Total DDT	5	0.117	0.014
Dieldrin	0.3	$2.50 \times 10^{-3}$	$3.07 \times 10^{-4}$
Heptachlor epoxide	0.3	$4.39 \times 10^{-3}$	$5.40 \times 10^{-4}$
Mercury	1.0	0.40	0.049
Mirex	0.1	0.80	0.098
	FDA Tolerance Level (ppm)		
PCBs	2	0.02	$2.45 \times 10^{-3}$

<sup>a</sup>U.S. FDA 1998.

noncarcinogenic and carcinogenic effects of the chemical contaminant, which are discussed in detail in Section 5 of this volume. EPA recommends that the more conservative of the calculated values derived from the noncarcinogenic rather than the carcinogenic effects be used because it is more protective of the consumer population (either recreational or subsistence fishers). As can be seen in Table 1-3 for the recreational fisher SV, the EPA-recommended values typically range from 2 to 120 times lower and are thus more protective than the corresponding FDA action or tolerance level. This difference is even more striking for subsistence fishers for whom the SVs are 20 to 997 times lower than the FDA values.

EPA and FDA have agreed that the use of FDA Action Levels for the purpose of making local advisory determinations is inappropriate. In letters to all states, guidance documents, and annual conferences, this practice has been discouraged by EPA and FDA in favor of EPA's risk-based approach to derive local fish consumption advisories.

EPA has provided this guidance to be especially protective of recreational fishers and subsistence fishers within the general U.S. population. EPA recognizes, however, that Native American subsistence fishers are a unique subsistence fisher population that needs to be considered separately. For Native American subsistence fishers, eating fish is not simply a dietary choice that can be completely eliminated if chemical contamination reaches unacceptable levels; rather, eating fish is an integral part of their lifestyle and culture. This traditional lifestyle is a living religion that includes values about environmental responsibility and community health as taught by elders and tribal religious leaders (Harris and Harper, 1977). Therefore, methods for balancing benefits and risks from eating

contaminated fish must be evaluated differently than for the general fisher population (see Section 5.1.3.2).

To enhance the use of this guidance as a working document, EPA will issue additional information and updates to users as appropriate. It is anticipated that updates will include minor revisions such as the addition or deletion of chemicals from the recommended list of target analytes, new screening values as new toxicologic data become available, and new chemical analysis procedures for some target analytes as they are developed. A new edition of this document will be issued to include the addition of major new areas of guidance or when major changes are made to the Agency's risk assessment procedures.

EPA's Office of Water realizes that adoption of these recommended methods requires adequate funding. In practice, funding varies among states and resource limitations will cause states to tailor their fish and shellfish contaminant monitoring programs to meet their own needs. States must consider tradeoffs among the various parameters when developing their fish contaminant monitoring programs. These parameters include

- Total number of stations sampled
- Intensity of sampling at each site
- Number of chemical analyses and their cost
- Resources expended on data storage and analysis, QA and quality control (QC), and sample archiving.

Consideration of these tradeoffs will determine the number of sites sampled, number of target analytes analyzed at each site, number of target species collected, and number of replicate samples of each target species collected at each site (Crawford and Luoma, 1993).

### 1.3 OBJECTIVES

The specific objectives of this manual are to

1. Recommend a tiered monitoring strategy designed to
  - Screen waterbodies (**Tier 1**) to identify those harvested sites where chemical contaminant concentrations in the edible portions of fish and shellfish exceed human consumption levels of potential concern (screening values [**SVs**]). SVs for contaminants with carcinogenic effects are calculated based on selection of an acceptable cancer risk level. SVs for contaminants with noncarcinogenic effects are concentrations determined to be without appreciable noncancer health risk. For a contaminant with both carcinogenic and noncarcinogenic effects, EPA recommends that the lower (more conservative) of these two calculated SVs be used.

- Conduct intensive followup sampling (**Tier 2, Phase I**) to determine the magnitude of the contamination in edible portions of fish and shellfish species commonly consumed by humans in waterbodies identified in the screening process.
  - Conduct intensive sampling at additional sites (**Tier 2, Phase II**) in a waterbody where screening values were exceeded to determine the geographic extent of contamination in various size classes of fish and shellfish.
  - Conduct intensive followup sampling in waterbodies where none of the 25 SVs are exceeded in order to establish areas of unrestricted fish consumption or “green areas.”
2. Recommend target species and criteria for selecting additional species if the recommended target species are not present at a site.
  3. Recommend target analytes to be analyzed in fish and shellfish tissue and criteria for selecting additional analytes.
  4. Recommend risk-based procedures for calculating target analyte screening values.
  5. Recommend standard field procedures including
    - Site selection
    - Sampling time
    - Sample type and number of replicates
    - Sample collection procedures including sampling equipment
    - Field recordkeeping and chain of custody
    - Sample processing, preservation, and shipping.
  6. Recommend cost-effective, technically sound analytical methods and associated QA and QC procedures, including identification of
    - Analytical methods for target analytes with detection limits capable of measuring tissue concentrations at or below SVs
    - Sources of recommended certified reference materials
    - Federal agencies currently conducting QA interlaboratory comparison programs.
  7. Recommend procedures for data analysis and reporting of fish and shellfish contaminant data.
  8. Recommend QA and QC procedures for all phases of the monitoring program and provide guidance for documenting QA and QC requirements in a QA plan or in a combined work/QA project plan.

## **1.4 RELATIONSHIP OF MANUAL TO OTHER GUIDANCE DOCUMENTS**

This manual is the first in a series of four documents to be prepared by EPA's Office of Water as part of a Federal Assistance Plan to help states standardize fish consumption advisories. This series of four documents—*Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories* includes

- Volume 1: *Fish Sampling and Analysis* (EPA 823-R-93-002), published August 1993; a second edition, published September 1995; and the current third edition (EPA-823-B-00-007) to be published in November 2000.
- Volume 2: *Risk Assessment and Fish Consumption Limits* (EPA 823-B-94-004), published June 1994; a second edition (EPA 823-B-97-009), published in July 1997; and a third edition (EPA-823-B-00-008) to be published in November 2000.
- Volume 3: *Overview of Risk Management* (EPA 823-B-96-006), published in June 1996.
- Volume 4: *Risk Communication* (EPA 823-R-95-001), published March 1995.

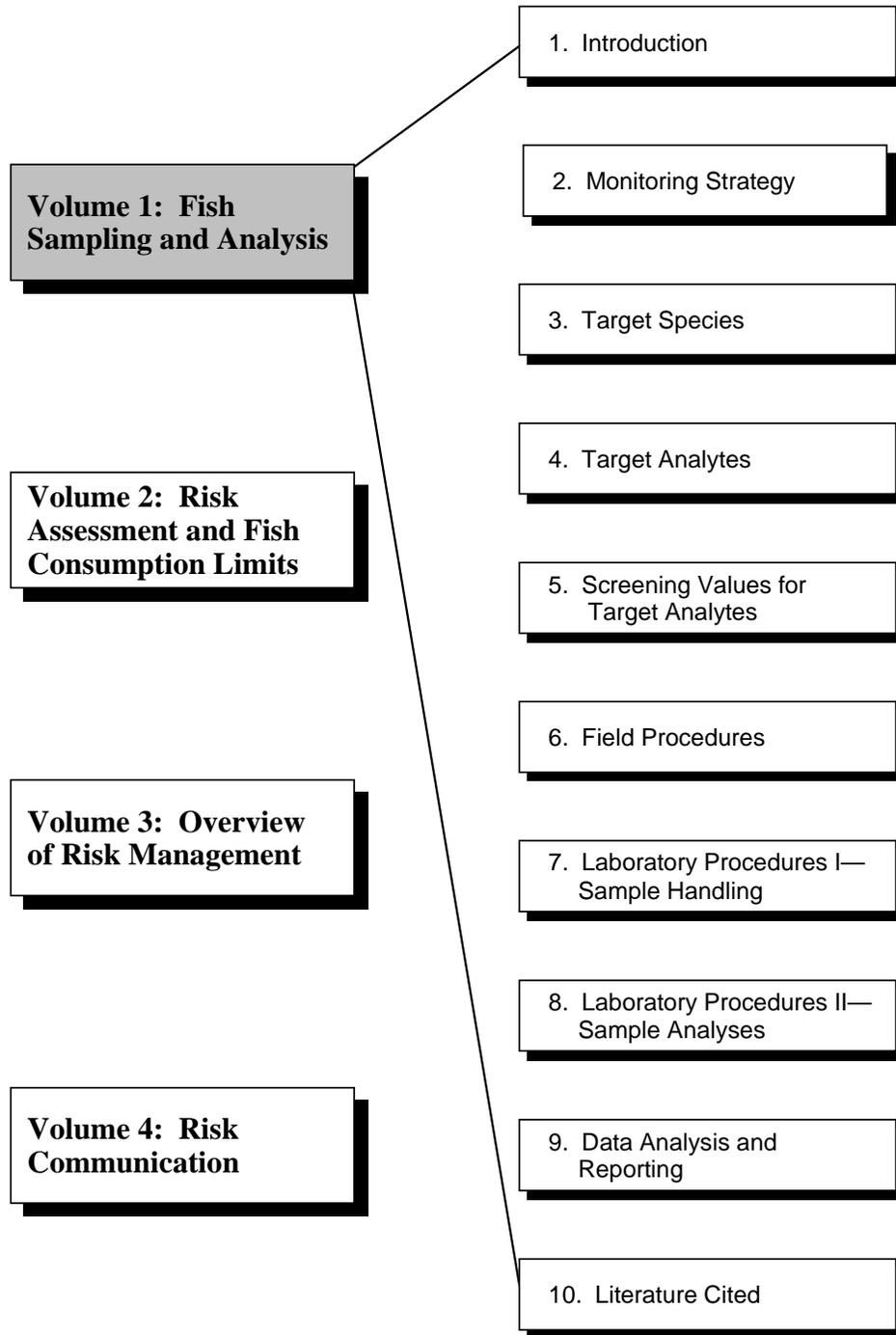
This sampling and analysis manual is not intended to be an exhaustive guide to all aspects of sampling, statistical design, development of risk-based screening values, laboratory analyses, QA and QC considerations, data analysis, and reporting for fish and shellfish contaminant monitoring programs. Key references are provided in Section 10, Literature Cited, that detail various aspects of these topics.

## **1.5 CONTENTS OF VOLUME 1**

Figure 1-3 shows how Volume 1 fits into the overall guidance series and lists the major categories of information provided. The first five sections discuss the history of the EPA Fish and Wildlife Contamination Program, monitoring strategy, including selection of target fish and shellfish species, selection of target analytes, and calculation of screening values for all target analytes. Section 6 provides guidance on field sampling and preservation procedures. Sections 7 and 8 provide guidance on laboratory procedures including sample handling and analysis, and Section 9 discusses data analysis and reporting procedures.

Appropriate QA and QC considerations are integral parts of each of the recommended procedures. Section 10 is a compilation of all literature cited in Sections 1 through 9 of this document. New information or revisions to existing information contained in previous editions of this guidance document are briefly described in Section 1.6.

Section 1 of this document reviews the historical development of this guidance document series, describes the purpose and objectives of the Volume 1 manual,



**Figure 1-3. Series summary: Guidance for assessing chemical contamination data for use in fish advisories.**

outlines the relationship of the manual to the other three documents in the series, describes the contents of the manual, and identifies new revisions made to the guidance of this third edition.

Section 2 outlines the recommended strategy for state fish and shellfish contaminant monitoring programs. This strategy is designed to (1) routinely screen waterbodies to identify those locations where chemical contaminants in edible portions of fish and shellfish exceed human health screening values, (2) sample more intensively those waterbodies where exceedances of these SVs have been found in order to assess the magnitude and the geographic extent of the contamination, and (3) identify those areas where chemical contaminant concentrations are low and would allow states to designate areas where unrestricted fish consumption may be permitted.

Section 3 discusses the purpose of using target species and criteria for selection of target species for both screening and intensive studies. Lists of recommended target species are provided for inland fresh waters, Great Lakes waters, and seven distinct estuarine and coastal marine regions of the United States.

Section 4 presents a list of recommended target analytes to be considered for inclusion in screening and intensive studies, briefly discusses the original criteria used in selecting these analytes, provides a summary of the toxicological information available for each analyte as well as pertinent information on the analyte's detection in national and regional fish monitoring studies.

Section 5 describes the new EPA risk-based procedure for calculating screening values for target analytes using (1) an adult body weight of 70 kg, (2) a lifetime exposure of 70 years, and (3) new consumption rate default values for both the general population and recreational fishers (17.5 g/d) and subsistence fishers (142.4 g/d). The last part of this section describes how to compare these new SVs against results obtained in fish tissue residue analysis.

Section 6 recommends field procedures to be followed from the time fish or shellfish samples are collected until they are delivered to the laboratory for processing and analysis. Guidance is provided on site selection and sample collection procedures; the guidance addresses material and equipment requirements, time of sampling, size of animals to be collected, sample type, and number of samples. Sample identification, handling, preservation, shipping, and storage procedures are also described.

Section 7 describes recommended laboratory procedures for sample handling including: sample measurements, sample processing procedures, and sample preservation and storage procedures.

Section 8 presents recommended laboratory procedures for sample analyses, including cost-effective analytical methods and associated QC procedures; and information on sources of certified reference materials; recommended analytical

techniques for target analytes, including revised detection and quantitation limits; information on the per-sample cost of chemical analysis for each target analyte; and information on federal agencies currently conducting interlaboratory comparison programs.

Section 9 includes procedures for data analysis to determine the need for additional monitoring and risk assessment and for data reporting.

Supporting documentation for this guidance is provided in Section 10, Literature Cited and in Appendixes A through N.

### 1.6 NEW INFORMATION AND REVISIONS TO VOLUME 1

This 3<sup>rd</sup> edition of Volume 1 contains newly prepared material as well as major updates and revisions to existing information. A brief summary of major additions and revisions is provided below.

#### Section 1

- New information is presented on the NLFWA database, including the 5-year trend in the total number of advisories issued nationwide, the number of advisories issued for five major pollutants of concern, and the issuance of increasing numbers of statewide advisories for freshwater lakes and/or rivers and coastal marine areas.
- Additional information describes the flexibility that is built into the EPA methodology, which allows the method to be used to meet a wide variety of state or tribal study needs within budgetary constraints.
- Clarification of the FDA methodology is provided emphasizing the inappropriateness of the method and reasons states should adopt and use the EPA methodology when issuing fish consumption advisories to protect their recreational and subsistence fishers.

#### Section 2

- Updated information is presented in Table 2-1 to be consistent with monitoring design and risk assumptions used in this 3<sup>rd</sup> edition.
- New discussion of the criteria states may use to identify green areas where chemical contaminant concentrations are at or below the screening values for recreational or subsistence fishers is introduced with more detailed information provided in Appendix B.

### Section 3

- Several tables, including Tables 3-7 and 3-19, were updated to include new information from the 1998 NLFWA database on the number of states that have issued fish advisories for freshwater and marine species.
- Table 3-9 was updated and associated narrative text was revised to include information on studies using turtles as biomonitors of environmental contaminants.

### Section 4

- Information on the environmental sources, toxicology, and the number of fish advisories issued in 1998 for each of the 25 target analytes was updated.
- New information is included on the range in concentrations of each contaminant detected in the FWS National Contaminant Biomonitoring Program and the EPA National Study of Chemical Residues in Fish as well as information on more recent regional studies.
- A procedure is described for the selection and prioritization of target analytes for analysis predicated on a watershed-based approach that takes into consideration land use categories, as well as geological characteristics, regional differences, national fish advisory trends, and monitoring and analysis costs.
- Additional guidance is presented on organophosphate pesticides and when and under what situations to monitor fish tissues for these compounds.
- A clarification is provided of the recommendation for selection of target species, especially bivalve molluscs and/or crustaceans when PAH contamination is suspected.
- A new discussion is provided to reflect the Agency's position on using Aroclor and congener analysis for calculating total PCB concentration.
- A new discussion is provided for determining the TEQ value for dioxins, which are now defined as including the 17 2,3,7,8 congeners of dioxin and 2,3,7,8 congeners of dibenzofuran, and the 12 coplanar PCBs with dioxin-like properties based on recent guidance from the World Health Organization (Van den Berg et al., 1998).
- Several tables, including Tables 4-1, 4-2, 4-7, and 4-9 were revised with new information. Tables 4-3, 4-4, 4-5, 4-6, and 4-8 are new to the document.
- All of the toxicological information was revised in light of the most current information concerning each target analyte.

### Section 5

- Revisions were made describing major changes in the assumptions used in the risk assessment equations to calculate screening values including use of default consumption rates of 17.5 g/d for the general population and recreational fishers and 142.4 g/d for subsistence fishers based on more recent information from the 1994 to 1996 Continuing Survey of Food Intake by Individuals study conducted by the U.S. Department of Agriculture.
- Additional guidance is provided on how states should handle the interpretation and risk assessment of chemicals that have detection limits higher than the risk-based screening values.
- Tables 5-1, 5-3, 5-4, and 5-5 were revised to reflect changes in consumption rates. Screening values shown in Tables 5-3 and 5-4 were developed using the new consumption rates as well as the most recent RfD and cancer slope factors available.
- Additional information is provided on Native American subsistence fishers, and Table 5-2 was added to summarize several recent studies on Native American fish consumption rates.
- Additional guidance is provided on how states should deal with interpreting analytical results in cases where the screening value is lower than the detection limit for a particular analyte.
- New guidance is provided on determining total PCBs by summary Aroclor equivalents or PCB congeners.
- New information from the World Health Organization (Van den Berg et al., 1998) is included in Table 5-6 showing the most recent Toxic Equivalency Factors (TEF) for the 2,3,7,8-substituted dioxins, dibenzofurans, and the 12 coplanar PCBs.

### Section 6

- Additional information is provided on the statistical implications associated with deviations from the recommended sampling design, including the use of unequal numbers of fish per composite, sizes of fish exceeding the size range recommendations for composites, and the use of unequal numbers of replicate samples across sampling sites.
- Clarification is provided on the recommended number of fish that should make up a composite sample.

- More explicit information is provided regarding exceedances of screening values and the statistical basis for issuing a new advisory or rescinding an existing advisory.
- Discussion is provided on the number of samples necessary to characterize different waterbody types and sizes of waterbodies with consideration given to the home range and mobility of the target species.
- How regional data should be used in the risk assessment process to address statewide advisories is discussed.
- Additional guidance is provided on how sample type selection should be based on the study objectives as well as on the sample type consumed by the target population.
- Clarification is provided as to EPA's position on the use of dead, lacerated, or mutilated fish for human health risk assessments.
- New information is provided on U.S. Fish and Wildlife Service and National Marine Fisheries permit requirements in situations where concerns exist about the impact of sampling for the target species in areas inhabited by threatened or endangered species.
- Revisions were made in recordkeeping for field sampling associated with use of the Year 2000 compliant format (YYYYMMDD) for sampling date information.

### Section 7

- Revisions were made in recordkeeping forms to initiate use of the Year 2000 compliant format for the date of sampling and analysis procedures.

### Section 8

- Updated information is included in Tables 8-1 through 8-5.
- Updated information is provided on the EPA Environmental Monitoring Methods Index System (EMMI).
- Revised information is provided in Section 8.3.3.8.1 concerning round-robin analysis interlaboratory comparison programs.

### Section 9

- New information is included on the National Tissue Residue Data Repository, now housed within the NLFWA database.

- Recommended data reporting requirements were updated (Figure 9-1) to include Year 2000 compliant format.
- Detailed information is provided on the Internet-based data entry facility contained within the NLFWA database that can accept fish contaminant residue data to support state fish advisories.
- An example of the new data tables (Figure 9-2) currently used in the fish tissue residue data repository is provided.

Section 10

- Literature citations were revised to include all new references cited in Sections 1 through 9.

Appendixes:

- The following appendixes were revised or added:
  - A - EPA 1993 Fish Contamination Workgroup Members
  - B - Screening Values for Defining Green Areas
  - D - Fish and Shellfish Species for Which State Consumption Advisories Have Been Issued
  - F - Pesticide and Herbicides Recommended as Target Analytes
  - G - Target Analyte Dose-Response Variables and Associated Information
  - I - Quality Assurance and Quality Control Guidance
  - M - Sources of Reference Materials